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Formulation and Evaluation of Herbal Effervescent Tablet

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KEYWORDS

Effervescent tablets, Gingerol, Flowability, effervescent time, angle of repose, bulk density, tapped density, Carr's index, Hausner ratio.

ABSTRACT

The study aims to obtain the best formulation for the production of effervescent tablets made from ginger as well as to determine their physicochemical characteristics. In present work an attempt has been made to formulate an effervescent tablet containing immediate release Gingerol using various acids and base. The effervescent tablets were prepared by wet granulation technique. Lactose as a binder and talc as lubricant were used. There are three formulations that content the citric acid and sodium bicarbonate were formulated.
These three formulations were evaluated for the flow ability of granules was evaluated, including flow rate, angle of repose, bulk density, tapped density, Carr's index, Hausner ratio, and effervescent time. The physical stability of granules such as organoleptic evaluation, effervescent time, and pH measurement was also evaluated after 28 d of storage. From above study it was concluded that F3 shows the better result than the F1 & F2.

1. INTRODUCTION

A pronounced focus on nutraceuticals and herbal medicines has been taken due to the escalating interest in health and well-being (1). Incorporating herbal extracts into conventional oral dosage forms usually venture challenges such as odor, unpleasant taste, and potential for incomplete absorption (2, 3). To triumph over these precincts and enhance patient compliance, the effervescent tablet has come into sight as a hopeful alternative (4-6). Effervescent tablets proffer numerous advantages, including rapid dissolution, the formation of a palatable and refreshing solution, and potentially improved drug absorption due to the release of carbon dioxide (7). These tablets are formulated with a mixture of acids (such as citric acid and tartaric acid) and bases (like sodium bicarbonate) that react in the presence of

water to produce carbon dioxide gas, leading to rapid disintegration and dissolution of the active ingredients (8).

Ginger contains major active constituents such as gingerol, shogaols and dehydrogingerdiones. Since ginger has antibacterial, antioxidant, [9, 10] anti-allergic, cardiotonic [11] antitumor [12, 13], antiinflamatory [14] , hepatoprotective [15] and antiemetic [16] activities. The main components of ginger rhizomes include terpenes, lipids, carbohydrates, and phenolic chemicals. Ginger contains phenolic chemicals like gingerol, paradols, and shogaol, as well as terpene components like zingiberene, β-bisabolene, α-farnesene, β-sesquiphellandrene, and α-curcumene. Zingiberene and bisabolene give ginger its distinct smell, while the volatile oils of gingerols and shogaols give it its strong flavor. Ginger also contains amino acids, raw fiber, ash, protein, phytosterols, vitamins, and minerals. Other compounds found in ginger rhizome include 6-paradol, 1-dehydrogingerdione, 6-gingerdione and 10-gingerdione, 4-gingerdiol, 6-gingerdiol, 8- gingerdiol, and 10-gingerdiol, and diarylheptanoids (17). figure 1 shows the structure of chemical constitutes of Zinger.

Ginger can be given safely upto 2-4 g per day dose. Making a ginger-based effervescent tablet involves combining ginger extract or powder with acid-base components and binders.

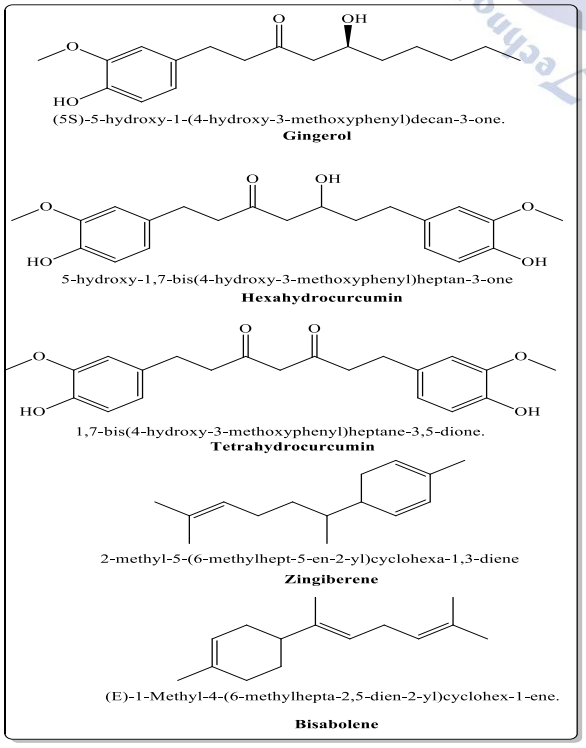

Figure 1. The structure of chemical constitutes of Zinger.

2. MATERIAL AND METHODS

Ginger (Zingiber officinale) was obtained from the local market. Sample collected from the local area of Parbhani.

The Excipients (Table 1) were collected from the laboratory of Shri Ramkrishna Paramhans College of Pharmacy, Hasnapur, Parbhani, Maharashtra, India.

Table No. 1. List Of Material Used

Sr No	Ingredient	Use
1.	Gingerol	analgesic and antipyretic
2.	Sodium bicarbonate	Effervescent agent
3.	Citric Acid	Effervescent agent
4.	Lactose	Binder
5.	Gelatin	Binder
6.	Starch	Glidant

The Instruments used for the formulation and evaluation are given in Table 2.

Table No. 2. List Of Instruments Used

Sr No	Instruments Used
1.	Electronic Weighing balance
2.	Sieve shaker
3.	Mortar Pestle
4.	Hot air oven
5.	Tablet Punching Machine
6.	Disintegration Apparatus
7.	Friabilator

Isolation of gingerol from ginger:

Dry ginger is crushed to form a powder. This power extract with 95% ethanol by simple maceration process then solvent was evaporated by distillation to obtain thick pasty mass. The thick pasty mass was suspended in water ginger resins precipitate in water and this precipitate is removed by filtration.

3. METHOD:

Drug (Gingerol), sodium bicarbonate were sieve through sieve No: 40#.Granules prepared with ethanol to form damp mass and it was passed through sieve no. 40#.

Citric acids, sodium bicarbonate, spray dried lactose, starch, gelatin was blended &passes through sieve no:

40#. Granules prepared by using binding agent (ethanol) & dry at 600c for 30 minute.

Both granules mix & dry at 60^{0}C for 15 minute. Granules were compressed into tablet by using single rotary tablet punching Machine.

Evaluation of Pre-compressed Blend (18, 19):

1) Angle of repose:

It was measured by fixed funnel method. The fixed funnel method employ a funnel that was secured with its tip at a given height "h", above graph paper that was placed on a flat horizontal surface. Granules were carefully poured through the funnel until the apex of the conical pile just touches the tip of the funnel. Thus, with "r" being the radius of the base of the conical pile.

$\tan\theta = h / r$

Where, θ=angle of repose

Table3: Flow Properties and Corresponding Angle of Repose

Flow Property	Angle of Repose
Excellent	25-30
Good	31-35
Fair	36-40
Passable	46-55
Poor	56-65
Very very poor	>66

2) Bulk density: an accurately weighed sample of granulation was carefully added to the measuring cylinder with the aid of funnel. The level was observed without compacting and noted as apparent volume (V0). The bulk density was calculated by the formula as given below:

Bulk density=M/V1

Where,

M=Mass of powder taken.

V0=Apparent untapped volume.

3) Tapped density: After bulk density measurement the cylinder was placed on the tapped density tester and was mechanically tapped. The cylinder was tapped 500 times initially and the tapped volume (V1) was measured to the nearest graduated units. The tapping was repeated for an additional 750 times and the tapped volume (V2) nearest to graduated units was noted.

The tapped density was calculated by the formula as given below:

Tapped density=M/V2

Where,

M=Weight of powder.

V2=Tapped volume (after750taps)

4) Carr's Index: The percentage compressibility of a powder is direct measure of the potential of powder arch or bridge strength is calculated according to the equation given below:

$$\% \text{ Compressibility index: } \frac{\text{Tapped density} - \text{bulk density}}{\text{Tapped density}} \text{ X } 100$$

5) Hausner's ratio:

Hausner found that the ratio tapped density/bulk density was related to inter particle friction as such, could be used to predict powder flow properties. The Hausner's ratio was calculated by the formula as:

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Table4: Flow ability according to compressibility & Hausner's Ratio

Compressibility Index	Flow Character	Hausner Ratio
≤10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very poor	1.46-1.59
≥ 38	Very very poor	>1.60

EVALUATION OF EFFERVESCENT TABLETS (18, 19)

1. Thickness

Thickness of the core tablets and coated tablets were measured by using screw gauge. Ten Tablets from each formulation were randomly selected and used. Thickness is expressed in Millimeters.

2. Hardness test

The hardness of the core tablets and coated tables were measured using the Pfizer hardness tester. Six tablets from each formulation were randomly selected

and used. The average hardness and the standard deviation were calculated. It is expressed in Kg/cm2.

Fig.1 Monsanto Hardness Tester

3. Friability test

Twenty tablets were weight and placed in the friability test apparatus and apparatus was rotated at 25 rpm for 4 min. After revolution the tablets were de-dusted and weight.

Percentage friability was calculated from the loss in weight as given in equation as below. The weight loss should not be more than 1%.

Fig.2 Friability Test Apparatus

4. Disintegration test

Disintegration test is carried out with the help of disintegration apparatus. Place 1 dosage unit in every tubes (six) of the basket, if prescribed use a disk. Use water as immersion fluid in not specified, maintained at 37o ± 2oC in immersion fluid. Operate the apparatus till each of the unit dosage come out from the basket, 15 minutes for uncoated tablets. 30 minutes for plain tablets, and 60 minutes for coated tablets and pills. If 1 or 2 tablets fail to disintegrate completely repeat the test on another 12 tablets, not less than 16 tablets of the total 18 tablets are disintegrated.

Fig.3 Disintegration Test Apparatus

5. Weight variation test

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated.

6. Content Uniformity

Twenty tablets were randomly selected from each batch and individually selected. The average weight and standard deviation of 20 tablets was analyzed. Tablets contain not less than 95% and not more than 105% of labeled amount of Gingerol.

7. Dissolution Test Apparatus:

A single tablet is placed in a small wire mesh basket attached to the bottom of the shaft connected to a variable speed motor. The basket is immersed in a dissolution medium (as specified in monograph) contained in a 100ml flask. The flask is cylindrical with a hemispherical bottom. The flask is maintained at 37±0.50C by a constant temperature bath. Thermometer is adjusted to turn at the specified speed and sample of the fluid are withdrawn at intervals to determine the amount of drug in solutions.

Fig. 4 Dissolution test apparatus

8. Measurement of effervescence time:

A single tablet is placed in a beaker containing 200ml of purified water at 20°C±1 °C. Whenever a clear solution without particles is obtained effervescence time has finished. The mean of three measurements of each formulation is to be reported.

9. Determination of effervescent solution pH:

pH of solution is determined with one tablet in 200 ml of purified water at 20 ± 1 °C by using pH meter,

immediately after completing the dissolution time. Repeat experiment 3times for each formulation.

10. Measurement of CO2 content:

One effervescent tablet solved in 100 ml of 1N sulphuric acid solution and weight changes were determined after dissolution end. The obtained weight difference is shown the amount (mg) of CO2 per tablet. Reports the averages of 3 determinations.

11. Evaluation of the water content:

10 tablets of each formulation are dried in a desiccators containing of activated silica gel for 4 hours. Water content of 0.5% or less is acceptable.

12. Uniformity of Content:

10 tablets were selected randomly. Each tablet was transferred into a 50mL volumetric flask, dissolved and diluted to50 mL with phosphate buffer pH 6.8.One ml of this solution was diluted to 100 ml with phosphate buffer pH 6.8. The amount of drug present in each tablet was determined by UV spectroscopy at 246 nm. Standard limit for uniformity of content is

IP: - Active less than 10 mg or 10%, BP:- Active less than 2 mg or 2%, USP: Active less than 25 mg or 25%.

- 10 tabs limit NMT 1 tab deviate 85–115% & none outside 75–125 % of the Avg value/IP/BP/USP (Relative Standard Deviation less than or equal to 6%),
- If 2 or 3 individual values are outside the limits 85 – 115% of the Avg value, & none outside 75 – 125% repeat for 20tablets.

13. Determination of the equilibrium moisture content:

Three desiccators are prepared containing saturated salt solutions of potassium nitrate (for creation 90% RH, at 18°C), sodium chloride (for creation 71% RH, at 18°C) and sodium nitrite (for creation 60% RH, at 18°C). Three tablets of each formulation are placed in desiccators. Then, the equilibrium moisture content is determined by Karl Fischer method and the auto titrat or device in the first day and after 7 day.

4. RESULT& DISCUSSION:

In present study the Gingerol effervescent tablet prepared by wet granulation method using various formulations (F1, F2, F3). These tablets were subjected to evaluation for drug content, friability test, disintegration test, hardness test and micromeritic properties like bulk density, tapped density, compressibility index and Hauser's ratio, in-vitro drug release studies.

Table 5: Evaluation of Granules

Property	F1	F2	F3
Bulk density G/cm³	0.76	0.72	0.73
Tapped density G/cm³	0.86	0.81	0.85
Angle of repose (⁰)	25.17	28.81	27.47
% Compressibility	11.63	11.11	14.11
Hausner's Ratio	1.13	1.12	1.18

Table 6: Evaluation of Tablets

Property	F1	F2	F3
Thickness(MM)	7.2	8.3	7
Disintegration Time (sec)	91±3	82±2	75±3
Hardness (kg/cm³)	2.3	2.1	1.8
Friability test (%)	96±0.2	95±0.3	98.02
Amount of drug content	76.5%	75%	76.6%
Weight variation	NMT2 tablets out of range	NMT2 tablets out of range	NMT2 tablets out of range

Disintegration Test Result:

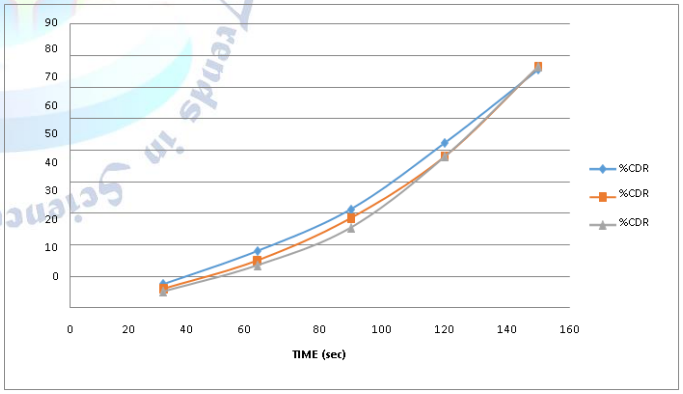

Fig. 5 In vitro release of Gingerol effervescent tablet.

From above graph (Fig:5) F3 shows the more drug release as compared to F1 & F2. Therefore it has been concluded that F3 shows better result.

5. CONCLUSION:

The study was under taken with an aim to formulate effervescent tablets of analgesic and antipyretic drug (Gingerol).The literature review showed that Gingerol having similar mechanism of action to aspirin because similarity in structure. Gingerol act by reducing production of prostaglandin which involved in pain and

Anti-inflammatory process, by inhibiting the cyclo-oxygenase enzyme.

In present work an attempt has been made to formulate an effervescent tablet containing immediate release Gingerol using various acids and base. The effervescent tablets were prepared by wet granulation technique. Lactose as a binder and talc as lubricant were used. There are three formulations that content the citric acid and sodium bicarbonate was formulated.

These three formulations were evaluated for hardness, friability, weight variation, and disintegration time and in-vitro drug release. From above study it was concluded that F3 shows the better result than the F1 & F2.

Conflict of interest statement

Authors declare that they do not have any conflict of interest.

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